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UNITED STATES DISTRICT COURT
 SOUTHERN DISTRICT OF NEW YORK

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 :
 LOUISE NARDELLA, : No.: 07 cv 8784 (SWK)
 :
 Plaintiff, : **ANSWER AND JURY DEMAND**
 : **OF DEFENDANT MERCK &**
 : **CO., INC.**
 :
 -against- :
 :
 MERCK & CO., INC., a Domestic Corporation, :
 :
 Defendant. :
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Defendant Merck & Co., Inc. ("Merck") answers the Complaint ("Complaint") herein as follows:

RESPONSE TO "STATEMENT OF THE PARTIES"

1. Denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 1, including subparagraph a, of the Complaint, except admits, upon information and belief, that Louise Nardella is a citizen of the State of New York.
2. Denies each and every allegation contained in paragraph 2 of the Complaint except admits that Merck is a New Jersey Corporation with its principal place of business in New Jersey and is authorized to do business in the State of New York and that Merck

manufactured, marketed and distributed the prescription medicine Vioxx until its voluntary withdrawal from the worldwide market on September 30, 2004.

3. Denies each and every allegation contained in paragraph 3 of the Complaint.

RESPONSE TO "STATEMENT OF THE FACTS"

4. Denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 4, including subparagraph a, of the Complaint.

5. The allegations contained in paragraph 5 of the Complaint are legal conclusions and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said sentences except admits that Merck is a New Jersey Corporation with its principle place of business at One Merck Drive, Whitehouse Station, New Jersey and that there is diversity jurisdiction and that Plaintiff purports to put more than \$75,000 in controversy but denies that there is any legal or factual basis for relief.

6. Denies each and every allegation contained in the first sentence of paragraph 6 of the Complaint except admits that Merck is authorized to do business in the State of New York. The allegations contained in the second and third sentences of paragraph 6 of the Complaint are legal conclusions to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said sentences except admits that there is diversity jurisdiction and that Plaintiff purports to put more than \$75,000 in controversy but denies that there is any legal or factual basis for relief.

7. Denies each and every allegation contained in paragraph 7 of the Complaint except admits that Vioxx is the brand name for rofecoxib and that Vioxx reduces pain and inflammation and the mechanism of action is believed to be due to inhibition of prostaglandin synthesis via inhibition of an enzyme known as cyclooxygenase-2 (COX-2) and that Merck marketed the prescription medicine Vioxx.

8. Denies each and every allegation contained in paragraph 8 of the Complaint.

RESPONSE TO "COUNT I – STRICT PRODUCTS LIABILITY"

9. With respect to the allegations contained in paragraph 9 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 8 of this Answer with the same force and effect as though set forth here in full.

10. Denies each and every allegation contained in paragraph 10 of the Complaint.

11. Denies each and every allegation contained in paragraph 11 of the Complaint.

12. Denies each and every allegation contained in paragraph 12 of the Complaint.

13. With respect to the allegations contained in paragraph 13 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 12 of this Answer with the same force and effect as though set forth here in full.

14. Denies each and every allegation contained in paragraph 14 of the Complaint.

15. Denies each and every allegation contained in paragraph 15 of the Complaint.

16. Denies each and every allegation contained in paragraph 16 of the Complaint.

17. Denies each and every allegation contained in paragraph 17 of the Complaint.

18. With respect to the allegations contained in paragraph 18 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 17 of this Answer with the same force and effect as though set forth here in full.

19. Denies each and every allegation contained in paragraph 19 of the Complaint except admits that Merck manufactured, marketed and distributed the prescription medicine Vioxx.

20. Denies each and every allegation contained in paragraph 20 of the Complaint.

RESPONSE TO “COUNT II – FRAUD”

21. With respect to the allegations contained in paragraph 21 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 20 of this Answer with the same force and effect as though set forth here in full.

22. Denies each and every allegation contained in paragraph 22 of the Complaint.

RESPONSE TO “COUNT III – NEGLIGENCE”

23. With respect to the allegations contained in paragraph 23 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 22 of this Answer with the same force and effect as though set forth here in full.

24. Denies each and every allegation contained in the first sentence of paragraph 24 of the Complaint. The allegations contained in the second sentence of paragraph 24 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained

in the second sentence of paragraph 24. Denies each and every allegation contained in the third and fourth sentences of paragraph 24 of the Complaint.

25. Denies each and every allegation contained in paragraph 25 of the Complaint.

26. Denies each and every allegation contained in the first and third sentences of paragraph 26 of the Complaint. The allegations contained in the second sentence of paragraph 26 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in the second sentence of paragraph 26.

RESPONSE TO “COUNT IV – NEGLIGENT MISREPRESENTATIONS”

27. With respect to the allegations contained in paragraph 27 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 26 of this Answer with the same force and effect as though set forth here in full.

28. Denies each and every allegation contained in paragraph 28 of the Complaint.

29. Denies each and every allegation contained in paragraph 29 of the Complaint, including subparagraphs a through f.

RESPONSE TO “COUNT V – EXPRESSED WARRANTY FOR GOODS”

30. With respect to the allegations contained in paragraph 30 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 29 of this Answer with the same force and effect as though set forth here in full.

31. Denies each and every allegation contained in the first, second and fourth sentences of paragraph 31 of the Complaint. The allegations contained in the third sentence of paragraph 31 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in the third sentence of paragraph 31.

RESPONSE TO “COUNT VI – IMPLIED WARRANTY”

32. With respect to the allegations contained in paragraph 32 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 31 of this Answer with the same force and effect as though set forth here in full.

33. Denies each and every allegation contained in paragraph 33 of the Complaint.

34. With respect to the allegations contained in paragraph 34 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 33 of this Answer with the same force and effect as though set forth here in full.

35. Denies each and every allegation contained in paragraph 35 of the Complaint.

RESPONSE TO “COUNT VIII – SURVIVAL ACTION”

36. With respect to the allegations contained in paragraph 39 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 35 of this Answer with the same force and effect as though set forth here in full.¹

37. Denies each and every allegation contained in paragraph 40 of the Complaint.

1. The Complaint omits paragraphs numbered 36 through 38. Merck has answered all paragraphs contained in the Complaint.

RESPONSE TO "DAMAGES"

38. Denies each and every allegation contained in paragraph 41 of the Complaint.

RESPONSE TO "PUNITIVE DAMAGES"

39. Denies each and every allegation contained in paragraph 42 of the Complaint.

RESPONSE TO "JURY DEMAND"

40. Plaintiff's "Jury Demand" section of the Complaint is not an allegation and therefore no responsive pleading is required.

RESPONSE TO "PRAYER"

41. Plaintiff's "Prayer" section of the Complaint, including subparagraphs 1 through 8, is not an allegation and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation in the "Prayer" section of Plaintiff's Complaint and denies that Plaintiff is entitled to the relief requested.

**AS FOR A FIRST
DEFENSE, MERCK ALLEGES:**

42. Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations and statutes of repose and is otherwise untimely.

**AS FOR A SECOND
DEFENSE, MERCK ALLEGES:**

43. The Complaint fails to state a claim upon which relief can be granted.

**AS FOR A THIRD
DEFENSE, MERCK ALLEGES:**

44. The claims of the Plaintiff may be barred, in whole or in part, from recovery because he has made statements or taken actions that preclude him from asserting claims or constitute a waiver of his claims.

**AS FOR A FOURTH
DEFENSE, MERCK ALLEGES:**

45. The claims of the Plaintiff may be barred, in whole or in part, from recovery because of the res judicata effect of prior judgments.

**AS FOR A FIFTH
DEFENSE, MERCK ALLEGES:**

46. Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

**AS FOR A SIXTH
DEFENSE, MERCK ALLEGES:**

47. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were cause in whole or in part through the operation of nature or other intervening cause or causes.

**AS FOR A SEVENTH
DEFENSE, MERCK ALLEGES:**

48. To the extent that Plaintiff asserts claims based on Merck's adherence to and compliance with applicable federal laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

**AS FOR AN EIGHTH
DEFENSE, MERCK ALLEGES:**

49. To the extent that Plaintiff asserts claims based upon an alleged failure by Merck to warn Plaintiff directly of alleged dangers associated with the use of Vioxx, such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to the prescribing physician.

**AS FOR A NINTH
DEFENSE, MERCK ALLEGES:**

50. If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were only so sustained after Plaintiff knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any drug or pharmaceutical preparation manufactured or distributed by Merck or other manufacturer.

**AS FOR A TENTH
DEFENSE, MERCK ALLEGES:**

51. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

**AS FOR AN ELEVENTH
DEFENSE, MERCK ALLEGES:**

52. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiff's misuse or abuse of Vioxx.

**AS FOR A TWELFTH
DEFENSE, MERCK ALLEGES:**

53. If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, subsequent medical conditions or natural courses of conditions for which this defendant is not responsible.

**AS FOR A THIRTEENTH
DEFENSE, MERCK ALLEGES:**

54. To the extent Plaintiff settled or will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, Merck's liability, if any, should be reduced accordingly.

**AS FOR A FOURTEENTH
DEFENSE, MERCK ALLEGES:**

55. To the extent Plaintiff is seeking recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action.

**AS FOR A FIFTEENTH
DEFENSE, MERCK ALLEGES:**

56. Plaintiff's claims of fraud are barred by reason of Plaintiff's failure to allege the circumstances constituting fraud with particularity, as required by Rule 9(b) of the Federal Rules of Civil Procedure.

**AS FOR A SIXTEENTH
DEFENSE, MERCK ALLEGES:**

57. Plaintiff's claims are barred, in whole or in part, under the applicable state law because Vioxx was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

**AS FOR A SEVENTEENTH
DEFENSE, MERCK ALLEGES:**

58. Plaintiff's claims are barred in whole or in part by the First Amendment.

**AS FOR A EIGHTEENTH
DEFENSE, MERCK ALLEGES:**

59. Plaintiff's claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

**AS FOR A NINETEENTH
DEFENSE, MERCK ALLEGES:**

60. There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of Vioxx.

**AS FOR A TWENTIETH
DEFENSE, MERCK ALLEGES:**

61. This case is more appropriately brought in a different venue.

**AS FOR A TWENTY-FIRST
DEFENSE, MERCK ALLEGES:**

62. The claims of Plaintiff may be barred, in whole or in part, from recovery because, in this or other courts, he has brought actions and has received judgments on parts of some or all claims asserted herein.

**AS FOR A TWENTY-SECOND
DEFENSE, MERCK ALLEGES:**

63. The claims of Plaintiff may be barred, in whole or in part, from recovery, on the ground that the claims asserted herein have been submitted to arbitration, and a binding decision has been rendered.

**AS FOR A TWENTY-THIRD
DEFENSE, MERCK ALLEGES:**

64. The claims of Plaintiff may be barred, in whole or in part, from recovery by release as to his claims.

**AS FOR A TWENTY-FOURTH
DEFENSE, MERCK ALLEGES:**

65. The claims of Plaintiff may be barred, in whole and in part, by the doctrine of laches.

**AS FOR A TWENTY-FIFTH
DEFENSE, MERCK ALLEGES:**

66. The claims of Plaintiff are barred, in whole or in part, by his failure to mitigate damages.

**AS FOR A TWENTY-SIXTH
DEFENSE, MERCK ALLEGES:**

67. To the extent there were any risks associated with the use of the product which is the subject matter of this action that Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and governing state laws.

**AS FOR A TWENTY-SEVENTH
DEFENSE, MERCK ALLEGES:**

68. The claims of Plaintiff may be barred, in whole or in part, from recovery, due to spoliation of evidence.

**AS FOR A TWENTY-EIGHTH
DEFENSE, MERCK ALLEGES:**

69. The claims of Plaintiff may be barred, in whole or in part, by the governing state laws.

**AS FOR A TWENTY-NINTH
DEFENSE, MERCK ALLEGES:**

70. Any conduct allegedly causing liability on the part of Merck is not a substantial cause or factor of any potential or actual injury or damage, if any.

**AS FOR A THIRTIETH
DEFENSE, MERCK ALLEGES:**

71. Plaintiff has not sustained any injury or damages compensable at law.

**AS FOR A THIRTY-FIRST
DEFENSE, MERCK ALLEGES:**

72. To the extent that Plaintiff seeks exemplary or punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, such an award would also, if granted, violate Merck's state and federal constitutional rights.

**AS FOR A THIRTY-SECOND
DEFENSE, MERCK ALLEGES:**

73. To the extent that Plaintiff seeks exemplary or punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless, or grossly negligent and, therefore, any award of exemplary or punitive damages is barred.

**AS FOR A THIRTY-THIRD
DEFENSE, MERCK ALLEGES:**

74. Plaintiff's demand for exemplary or punitive damages is barred because Vioxx and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

**AS FOR A THIRTY-FOURTH
DEFENSE, MERCK ALLEGES:**

75. Plaintiff's claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

**AS FOR A THIRTY-FIFTH
DEFENSE, MERCK ALLEGES:**

76. Plaintiff's claims are barred in whole or in part because Merck provided adequate "directions or warnings" as to the use of Vioxx and any other drug or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

**AS FOR A THIRTY-SIXTH
DEFENSE, MERCK ALLEGES:**

77. Plaintiff's claims are barred under Section 4, et. seq., of the Restatement (Third) of Torts: Products Liability.

**AS FOR A THIRTY-SEVENTH
DEFENSE, MERCK ALLEGES:**

78. Plaintiff's claims are barred in whole or in part because Vioxx "provides net benefits for a class of patients" within the meaning of comment f to Section 6 of the Restatement (Third) of Torts: Product Liability.

**AS FOR A THIRTY-EIGHTH
DEFENSE, MERCK ALLEGES:**

79. Plaintiff's claims are barred by the doctrine of contributory negligence.

Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Merck to determine all of its legal, contractual and equitable rights, Merck reserves the right to amend and supplement the averments of its answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery of this action.

Merck will rely on all defenses that may become available during discovery or trial.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck its reasonable costs and disbursements, together with such and other and further relief that the Court may deem just and proper.

JURY DEMAND

Merck demands a trial by jury as to all issues so triable.

DATED: New York, New York
October 30, 2007

Respectfully submitted,

HUGHES HUBBARD & REED LLP

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